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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,810	03/01/2006	Masaaki Uenaka	SHIOP0100US	8381

7590 07/13/2009
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EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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07/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,810	Applicant(s) UENAKA, MASAOKI	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/27/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The last phrase is unclear: two or more what? Solvating molecules or compounds? In the latter case, one would have a mixture of say, a compound which is a butanol solvate and a compound which is a 1-propanol solvate. In the former case, there is a compound which is a double solvate of two different alcohols.

Claims 1-5, 7, 9, 11, 13, 15-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the solvates prepared, does not reasonably provide enablement for other solvents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

If there is intended the double solvates, these are not enabled. Double solvates of two different organic solvents are quite uncommon, and applicants have not shown that

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they can make such compounds. In fact, it's not clear that applicants have even contemplated them.

If there are intended mixtures of two different solvates, e.g. Compound I as a 1-pentanol solvate mixed with Compound I as an isopropanol solvate, where are these described?

Claims 1-2, and 7-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1-propanol, does not reasonably provide enablement for other solvents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Example 7 used 2-pentanol, and example 8 has 1-pentanol and example 9 has t-amyl alcohol and example 10 has 1-propanol. But the actual products are solvates of both water and the alcohol. Such compounds do not fall within claim 1. That is, while one might have expected a solvate of 1-pentanol from example 7, in fact, the product is listed as a hydrate-solvate, and thus, applicants have not shown that a straight solvate with 1-pentanol can be formed.

Claims 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

See preceding rejection. The compounds of claims 7, 9, 11, and 13 are not described correctly. These are actually solvate hydrates, not just solvates. Changing the name would fix the problem.

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Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compound or crystal, does not reasonably provide enablement for the solvate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants have shown that the esters form solvates, at least with some alcohols. However, applicants have not shown that Formula II, which is an acid, forms the hydrate of claim 19.

Specification

Examples 7-10 of the specification are objected to. These examples appear to be defective. The compounds are listed as being hydrates, and yet water was not used. For example, the analysis for example 7 lists the compound as having 2 ½ moles of water per mole of the β -lactam. Where did all this water come from? Note that compound (I) is not listed as being a hydrate.

Claim Objections

Claim 19 is objected to as improperly dependent on claim 17. Claim 17 no longer provides for solvates. Claim 19 should be canceled.

Claims 7-14 are improperly dependent on claim 1, which does not provide for hydrates, which, according to the specification, is what these materials really are.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/
Primary Examiner
Art Unit 1624

7/10/2009